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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 734,786	12/11/2000	Norimitsu Saito	312762002400	4706

25225 7590 07/21/2003

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	18

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/734,786	SAITO ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *30 June 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s)

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-8,11,13-15,17 and 19*

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *15*.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): the objection to the specification is withdrawn in view of Applicant's clarification. The amendments to the specification have been entered.

Continuation of 5. does NOT place the application in condition for allowance because In response to the outstanding rejection under 35 U.S.C. §112, first paragraph, as lacking enablement, Applicant characterizes the Examiner's position as follows: "the Office asserts that the invention has no 'real world' utility. The basis for his appears to be the assertion that there is no value in inserting nucleic acids into tissues. The basis for this, in turn, appears to be that gene therapy is in its early stages and that although it is clear it might be desirable to introduce nucleic acids into mammalian subjects, and there are thousands of scientists engaged in this work, a contribution to the efforts of these scientists is inherently un-useful unless individuals are actually cured by such therapy" (page 2).

Applicant argues that this position is in error stating, "there are a number of instances in which individuals have, in fact, benefited from 'gene therapy'" and "[i]t is recognized that such therapies are not routine and that unfortunate side effects have occurred; this does not mean that the entire field is forever doomed to failure or that contributions to this field are, therefore, unuseful" (page 3).

Applicant is reminded that the enabling disclosure must teach the skilled artisan how to use the claimed invention without having to first engage in experimentation beyond what would be considered routine in the art. It must be pointed out that the Examiner has not asserted that the specification has not set forth a patentable utility for the claimed invention, in which case the claims would have been rejected under 35 U.S.C. §101, which they were not. Nor has the Examiner asserted that the entire field of gene therapy is doomed to failure. The Examiner's position is based on the requirement that Applicants not only set forth a specific, substantial and credible utility for the claimed invention, which has been done in the instant case, but also enable the skilled artisan to use the invention for that stated purpose without engaging in undue experimentation. The specification explicitly contemplates using the claimed method to affect the growth or quality of hair and for immunization, and as an intermediate step in genetic therapy of a whole organism (see especially page 4, second full paragraph). However, for reasons of record, the teachings of the specification and prior art would not enable the skilled artisan to use the claimed method for these purposes without engaging in undue experimentation. Applicant states, "[i]t is well-recognized that both gene therapy and generation of an immune response by in situ production of proteins are viable approaches to therapy and prophylaxis and will be routine in the relatively near future" (page 3). However, in Paper No. 10, the examiner cites several teachings from the art to support the position that at the time of filing gene therapy according to the instant claimed method would not be possible without additional, and undue, experimentation. Applicant has produced no evidence to the contrary, and it is noteworthy that Applicant's statement that gene therapy will be routine in the relatively near future is made more that three and one-half years after the effective filing date of the instant application.

With regard to the utility of the claimed method as a research tool, Applicant argues in the second full paragraph on page 3, "the invention as described in Example 2 permits optimization of the claimed technique which is, itself, fully developed." In other words, it would seem that Applicant is arguing that the claimed invention can be used to optimize the claimed technique. As pointed out on page 4 of the Final Office Action mailed 25 March 2003, an asserted utility that amounts to...improving the invention does not constitute a patentable utility. Therefore, the only patentable utility asserted for the claimed invention is gene therapy, which for reasons of record is not enabled by the disclosure. Furthermore, even if an enabled utility had been identified, the claimed methods still encompass gene therapy and would not, therefore, be enabled for the full scope of the claimed subject matter. Thus, for reasons of record in previous office actions and herein above, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement.

JAMES KETTER
PRIMARY EXAMINER